Essai Clinique

Généré le 12 mai 2024 à partir de

Titre	A Phase 2 Basket Study of Disitamab Vedotin in Adult Subjects With Previously Treated, Locally-Advanced Unresectable or Metastatic Solid Tumors That Express HER2
Protocole ID	SGNDV-005
ClinicalTrials.gov ID	NCT06003231
Type(s) de cancer	Tumeurs solides
Phase	Phase II
Stade	Maladie avancée ou métastatique
Type étude	Clinique
Médicament	Disitamab Vedotin
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DE L'ENFANT-JESUS 1401 18e Rue, Québec, QC, G1J 1Z4
Ville	
Investigateur principal	Dr Vincent Castonguay
Coordonnateur	Maryse Gingras 418-525-4444 poste 67322
Statut	Actif en recrutement
Date d'activation	06-10-2023
But étude	This clinical trial is studying advanced or metastatic solid tumors. Once a solid tumor has grown very large in one spot or has spread to other places in the body, it is called advanced or metastatic cancer. Participants in this study must have head and neck squamous cell cancer, non-small cell lung cancer, endometrial cancer, or ovarian cancer. Participants must have tumors that have a marker called HER2. This clinical trial uses an experimental drug called disitamab vedotin (DV). DV is a type of antibody-drug conjugate or ADC. ADCs are designed to stick to cancer cells and kill them. In this study, all participants will get DV once every 2 weeks.This study is being done to see if DV works to treat different types of solid tumors that express HER2. It will also test how safe the drug is for participants. This trial will also study what side effects happen when participants get the drug. A side effect is anything a drug does to your body besides treating the disease.

Critères d'éligibilité	• **Cohort 1: HNSCC**
	  • Pathologically-documented squamous cell carcinoma of the head and neck with primary tumor site arising from the oral cavity, oropharynx, hypopharynx, and larynx
	  • Unresectable locally recurrent or metastatic stage disease
	  • Prior therapies:
	  • Participants must have disease progression after treatment with a platinum-based therapy
	  • No more than 1 line of cytotoxic chemotherapy for advanced disease
	• **Cohort 2: NSCLC**
	  • Pathologically documented NSCLC
	  • Unresectable locally-advanced or metastatic stage disease
	  • Prior therapies
	  • Must have progressed during or after a platinum-based therapy or, within 6 months of platinum-based adjuvant, neoadjuvant, or concomitant chemoradiotherapy for early or locally-advanced stage disease

	• Must have received prior anti-PD(L)1 therapy, unless contraindicated • No more than 2 prior lines of cytotoxic chemotherapy for advanced disease • **Cohort 3: Ovarian Cancer** • Pathologically documented epithelial cancers of ovarian, fallopian tube, or peritoneal origin • Unresectable locally-advanced or metastatic stage disease • Prior therapies • Must have platinum resistant disease (6 months or less between the completion of platinum-based treatment and identification of recurrence) • Must not have received more than 4 lines of prior cytotoxic chemotherapies for advanced disease • May have received prior anti-PD(L)1 therapy • **Cohort 4: Endometrial Cancer** • Must have pathologically documented adenocarcinoma of the endometrium • Must have unresectable locally-advanced or metastatic stage disease. • Prior therapies • Must have relapsed/progressed after at least one prior platinum-based chemotherapy for recurrent, metastatic or primary unresectable disease • Must not have received more than 3 lines of prior cytotoxic chemotherapies for advanced disease • May have received prior anti-PD(L)1 therapy • HER2 expression of 1+, 2+, or 3+, as determined by local IHC testing on a fresh or archival tumor tissue • Measurable disease per RECIST v1.1 criteria as assessed by the investigator • Able to provide formalin-fixed, paraffin-embedded (FFPE) tumor tissue blocks (or freshly sectioned slides) • Eastern Cooperative Oncology Group (ECOG) performance status score of 0 or 1
Critères d'exclusion	• Prior treatment with an MMAE-containing agent. • Previous treatment with HER2-directed ADCs • Known hypersensitivity to any excipient contained in the drug formulation of disitamab vedotin. • History of another invasive malignancy within 2 years before the first dose of study intervention, or any evidence of residual disease from a previously diagnosed malignancy. • Active untreated CNS or leptomeningeal metastasis